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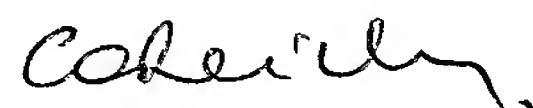
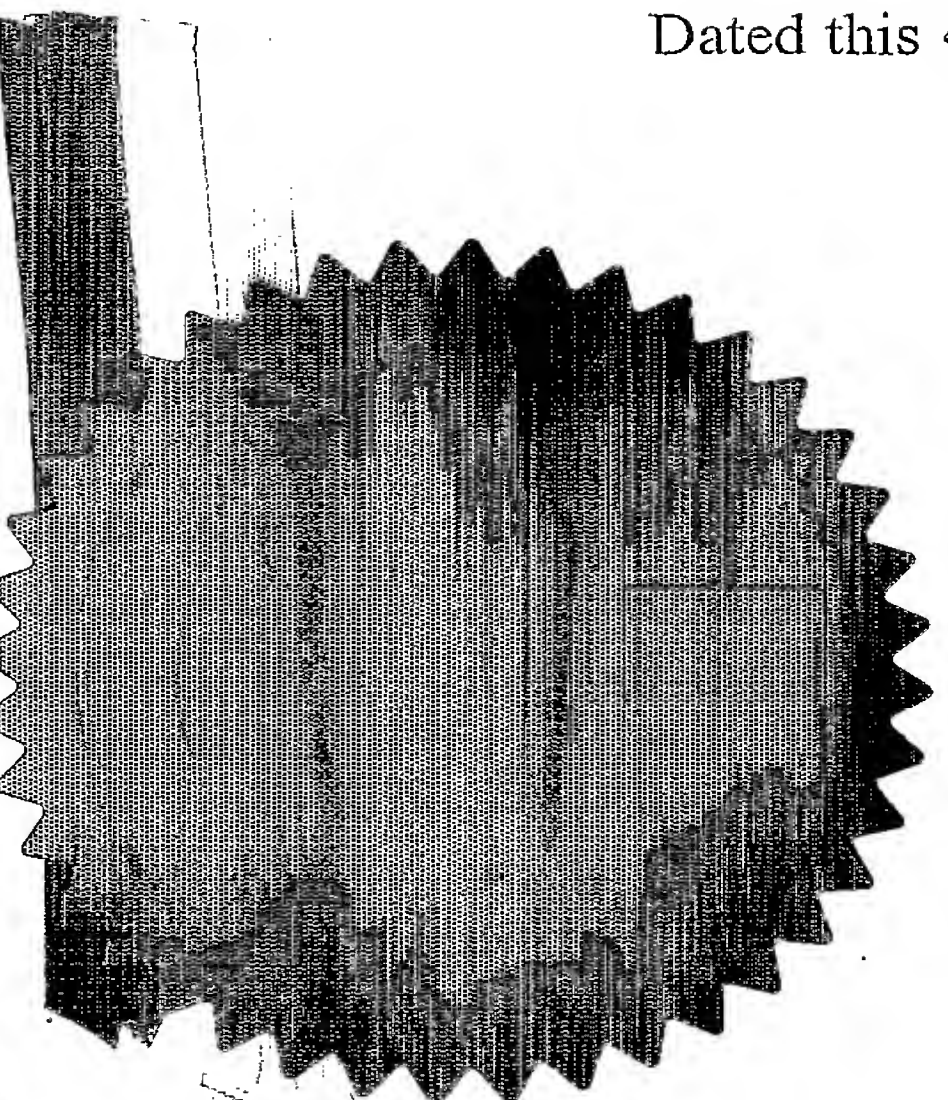
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Application No. S2003/0961

Date of Filing 22 December 2003

Applicant EAMON BRADY, an Irish citizen of Doon,
Kilrickle, Loughrea, County Galway. Ireland.

Dated this 5 day of January 2005



An officer authorised by the
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5030961

FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT 1992

The Applicant(s) named herein hereby request(s)
[] the grant of a patent under Part II of the Act
[X] the grant of a short-term patent under Part III of the Act
on the basis of the information furnished hereunder.

1. Applicant(s)

BRADY, Eamon
Doon
Kilrickle
Loughrea
County Galway
Ireland
an Irish citizen

2. Title of Invention

Improvements in medical device packaging

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

<u>Previous Filing</u> <u>Date</u>	<u>Country in or for</u> <u>which filed</u>	<u>Filing No.</u>
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4. Identification of Inventor(s)

Name(s) and adresse(s) of person(s) believed by the Applicant(s) to be the inventor(s)
Eamon Brady
an Irish Citizen of Doon, Kilrickle, Loughrea, County Galway, Ireland

5. Statement of right to be granted a patent (Section 17(2) (b))

6. Items accompanying this Request

- (i) [X] prescribed filing fee (Euro 60.00)
- (ii) [] specification containing a description and claims
[X] specification containing a description only
[X] Drawings referred to in description or claims
- (iii) [] An abstract
- (iv) [] Copy of previous application(s) whose priority is claimed
- (v) [] Translation of previous application whose priority is claimed
- (vi) [] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. Divisional Application(s)

The following information is applicable to the present application which is made under Section 24 -

Earlier Application No.
Filing Date:

8. Agent

The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted -

Name & Address

Cruickshank & Co. at their address recorded for the time being in the Register of Patent Agents is hereby appointed Agents and address for service, presently 1 Holles Street, Dublin 2.

9. Address for service (if different from that at 8)

Signed Cruickshank & Co.

By:-

C. Schmitt

Agents for the Applicant

Executive.

Date December 22, 2003.

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"Improvements in Medical Device Packaging"Introduction

The present invention relates to a medical device package and in particular to a catheter guide wire packaging device.

5 Such guide wire packaging devices generally comprise a thermoplastic tube having a bore for reception of the wire and some means for securing the packaging device in position by spirally winding it around itself and securing it together. This latter form of packaging device is
10 extensively used and has many advantages in that the coil formed by the packaging device containing the wire can be held firmly together and there is no overlapping of the wire onto itself. There is no internal contact of the wire coils so that there would be no surface damage or
15 contamination and finally if the packaging device is manufactured from a low friction material such as polyethylene, damage is virtually eliminated during handling. This is the type of packaging used for the majority of medical guide wires sold at present.

20 When it is considered that nearly 10 million units of guide wires are sold every year and guide wires are relatively delicate instruments, it can be appreciated that anything that can reduce the cost of packaging the guide wires and at the same time provide a more efficient
25 packaging is of considerable importance. Thus, while the present guide wire packaging device, often referred to as a guide wire dispenser, has been on the market for several years and performs the task adequately it is not optimal.

30 One of the important features in the design of such a guide wire packaging device and in particular a packing

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device for catheter wires is that it is essential that when wound, the diameter of the innermost coil of the spiral hoop so formed is not so small as to allow the wire to set into a particular configuration or deform by kinking. There is thus a minimum internal diameter to which the guide wire dispenser's innermost coil can be formed. The outside diameter of the final assembly is dependent on this minimum internal diameter, the length of the tube and the magnitude of the gap between the coils. The length of the guide wire can be as much as 300 cm and the gap between the coils of most present constructions is 2 mm.

At the same time there are some disadvantages in the present construction of catheter wire dispenser in that they are relatively expensive to produce and as there are a large number of components, assembly is expensive and time-consuming.

The present construction of catheter wire dispenser incorporates a fastener snap-fit mount which does not consistently hold the coils in an ideal configuration. Adjacent coils in an assembly can slide and rotate relative to one another. This gives the coils 2 degrees of freedom in respect of available movements. If the coils slide relative to one another, then the gap between the coils will vary throughout the assembly from as little as 0 mm to as much as 10 mm or 15 mm. If the coils rotate in the snap-fit mount, then the planarity of the assembly is lost. One of the negative affects of these movements is that the volume occupied by the package is large and variable. Another disadvantage of these movements is that they put stress on the snap-fit mount joints and these frequently fail under load with the result that the guide wire dispenser is presented to the physician in an undesirable configuration. Ideally such a catheter wire

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dispenser would use the minimum amount of plastics and have less bulk construction of dispenser.

5 A further problem with the present construction of guide wire packaging is the necessity to provide the attachment of the hoop to a fluid flushing device such as a syringe. Such fluid flushing devices are required to ensure that prior to use the guide wire can be washed in saline or some other solution. This is usually achieved by flushing fluid through the packaging tube. It is therefore
10 necessary to connect the tube to a fluid dispensing device and this is achieved by attaching a luer to the end of the guide wire packaging device.

A significant disadvantage of the present construction of luer is that it does not grip the tube sufficiently
15 tightly to prevent rotation as the fluid flushing device is being screwed into position.

The present invention is directed towards providing an improved construction for medical device packaging and in particular to providing a catheter wire dispensing device
20 and further for providing an adapter for connecting such a guide wire packaging device to a flushing device.

Statements of Invention

According to the invention there is provided a guide wire packaging device of the type comprising a flexible tube
25 having a bore for reception of the wire, characterised in that the tube has formed on the exterior surface thereof engagement means to permit interengagement when the tube is wound on itself. The flexible tube is preferably formed from a thermoplastic material. It will be
30 appreciated that the advantage of this arrangement is that since the tube is wound closely to itself that the

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packaging of the tubing will be much smaller than heretofore has been possible with currently available devices.

5 Ideally the engagement means comprises male and female cooperating members.

10 A further advantage is that if the male and female engagement means project around the whole of the tube, this means that the hoop so formed when the tube is spirally wound will maintain its planarity at all times and further will allow that the product be presented to the physician in the correct configuration at all times, and as a medical product this is an important consideration.

15 A further advantage of the male and female engagement means is that there is no degree of freedom of movement available to coils relative to one another and thus the space occupied by a guide wire packaging assembly is constant, even if the package comes under the influence of handling loads.

20 A further advantage of the device is that since the hoop is comprised of only one component, the assembly of the guide wire packaging devices according to this invention can be carried by machinery in an automated fashion.

25 In one embodiment of the invention, the male and female members are alternatively arranged around the periphery of the tube. The male and female members are preferably arranged on opposite sides of the tube. This is a particularly suitable configuration. For example, in one embodiment of the invention, there is one set of male
30 members and one set of female members on radially opposite

- 5 -

sides of the tube. Ideally there is a pair of male members and a pair of female members in each set.

5 In one embodiment of the invention the engagement means comprises a longitudinally arranged groove and a radially opposite, longitudinally arranged upstanding rib on the tube, the upstanding rib being dimensioned to form a force-fit within the groove.

10 In a preferred embodiment of the invention, the groove is re-entrantly shaped. This particularly simple construction will be more than adequate in many situations.

In a still further embodiment of the invention, there is provided an adapter for connecting the tube to a fluid flushing device comprising:

15 a body member;

connectors in the body member engaging with the fluid flushing device;

a bore in the body member for alignment of the bore with the tube;

20 reception means in the body member for the engagement means to lock the wire packaging device within the adapter.

25 In a further embodiment of the invention, the thread and luer lock taper for attachment of the fluid flushing device is integrated into the end of the tube of the medical packaging device. This construction is achieved by forming the thread and taper on the end of the tube.

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This is a particularly suitable configuration as it overcomes all the issues of rotation and leakage.

5 Ideally the fluid flushing is achieved by using an ANSI luer connection. The particular advantage of the present invention is that it overcomes the problems of more conventional connection devices when difficulties are often encountered when trying to lock the adapter on the tube. This specifically refers to rotation of the conventional luer attached to the dispenser being loaded rotationally during the connection of a syringe or other device.

10

Detailed Description of the Invention

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only with reference to the accompanying drawings, in which:-

15

Fig. 1 is a perspective view of portion of a medical packaging device;

Fig. 2 is a typical cross-sectional view of the medical packaging device of Fig. 1;

20

Fig. 3 is a side view of the medical packaging device of Fig. 1 and 2;

Fig. 4 is a cross-sectional view along the lines IV-IV of Fig. 3;

Fig. 5 is a side view of an adapter for use with the invention;

25

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Fig. 6 is a cross-sectional view of the adapter of Fig. 5;

5

Fig. 7 is a typical cross-sectional view through the adapter of Fig. 5 when assembled on a tube of a medical packaging device according to the invention;

Fig. 8 is a typical cross-sectional view of an alternative construction of adapter according to the invention;

10

Fig. 9 is a sectional view through the adapter of Fig. 8 mounted on a medical packaging device according to the invention;

Fig. 10 is a view similar to Fig. 9 of an alternative construction of adapter;

15

Fig. 11 is a view similar to Figs. 9 and 10 of a still further construction of adapter according to the invention;

Fig. 12 is a cross-sectional view of an alternative construction of medical packaging device;

20

Fig. 13 is a cross-sectional view of a further alternative construction of medical packaging device;

Fig. 14 is a cross-sectional view of another construction of medical packaging device;

Fig. 15 is a cross-sectional view of a further construction of a medical packaging device; and

25

Fig. 16 is a cross-sectional view of another construction of a medical packaging device.

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Referring to the drawings and initially to Figs. 1 to 4 thereof, there is provided a medical packaging device according to the invention indicated generally by the reference numeral 1, comprising a flexible tube 2 of a plastics material having a bore 3 for reception of a catheter wire indicated in the drawings by the reference numeral 4. Mounted on the exterior surface of the tube 2 is an engagement means provided by a pair of spaced apart male members 5 and female members 6. In use when a catheter wire 4 is placed within the bore 3 and the tube 2 wound around itself as illustrated in Fig. 3, the male members 5 engage the female members 6 and the medical packaging device 1 is locked in position as illustrated clearly in Fig. 4.

Referring to Figs. 5 and 6, there is illustrated an adapter for connecting the medical packaging device 1 of Figs. 1 to 4, to a luer fluid flushing device. The adapter is indicated generally by reference numeral 10 and comprises a body member 11 terminating at one end in a threaded head 12 for connection to the luer device and having a tapered bore portion 13 connecting with a lumen 14 and then an enlarged stepped bore portion 15 for reception of a tube 2. At the distal end of the body member 11 there is provided four spaced apart slots 16 for reception of the male members 5 and female members 6 as can be seen in Fig. 7.

It will be noted that the bore portion 15 terminates in an annular recess 17 for reception of the end face of the tube 2.

It will be appreciated that with this embodiment of the invention that by a careful use of the correct dimensions, the female members 6 may be used to secure the tube 2

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5 firmly to the body member 11 through the slots 16. Similarly, the male members 5 may perform the same task. The advantage is that both the male and female members being of plastics materials will deform relatively easily and thus the manufacturing tolerances for the adapter 10 do not have to be high.

10 Alternatively either the male or female members could be formed with some form of interference fit to secure the adapter 10 more securely to the medical packaging device 1.

As an alternative if the bore portion is correctly dimensioned relative to the tube 2, the necessary force-fit can be achieved.

15 Referring to Figs. 8 and 9 there is illustrated an alternative construction of adapter indicated generally by the reference numeral 20 with parts similar to those described with reference to the previous drawings identified by the same reference numerals. In this embodiment there is provided a bore portion 15 in the bore of the adapter 20 which is so arranged as to receive all of the tube 2 as can be seen clearly from Fig. 9.

25 Referring to Fig. 10, there is illustrated a further construction of adapter indicated generally by the reference numeral 30 in which parts similar to those described with reference to the previous drawings are identified by the same reference numerals. In this embodiment of the invention the adapter 30 is provided with protrusions 31 to facilitate the gripping of the adapter 30.

30 Fig. 11 illustrates a still further construction of adapter indicated generally by the reference numeral 40

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in which the adapter 40 has a body member 41 having opposed flat surfaces 42 to facilitate gripping.

5 In another embodiment the threaded head 12 and the tapered bore portion 13 of the adapter body may be formed on the end of the tube 2 of the medical packaging device. This eliminates the need for a separate adapter while still facilitating the attachment of a flushing device.

Referring to Figs. 12 to 16 there are shown a series of alternative constructions of medical packaging device.

10 Referring to Fig. 13 there is shown an alternative construction of medical packaging device 40 in which a single male member 41 engages in two female members 42. A further feature of this construction is the creation of a second lumen or bore 3. This facilitates the protection
15 of a second medical device within the one configuration.

Referring to Fig. 14 there is shown an alternative construction of medical packaging device 50 in which the male members 5 and female members 6 are spaced wider apart.

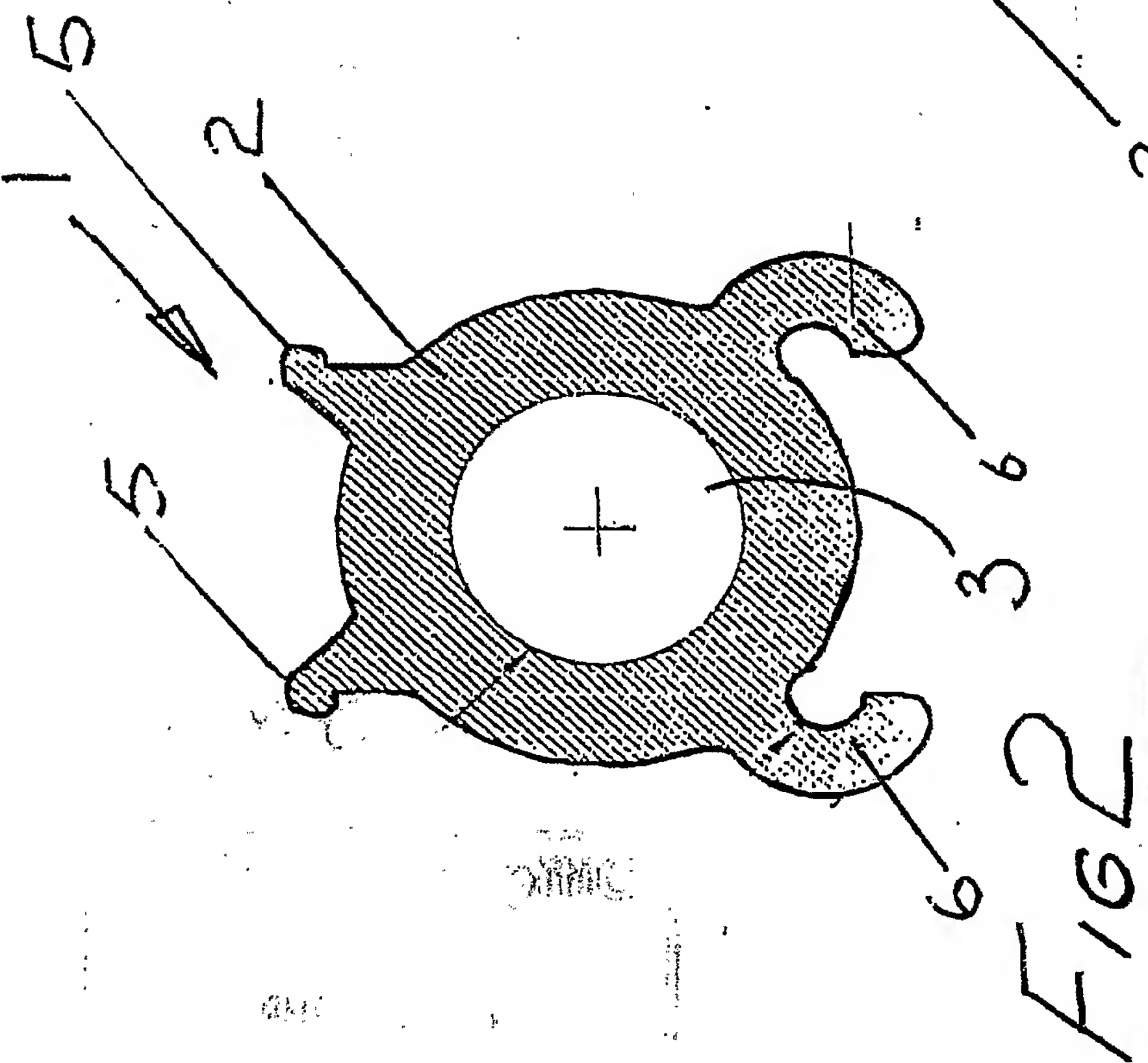
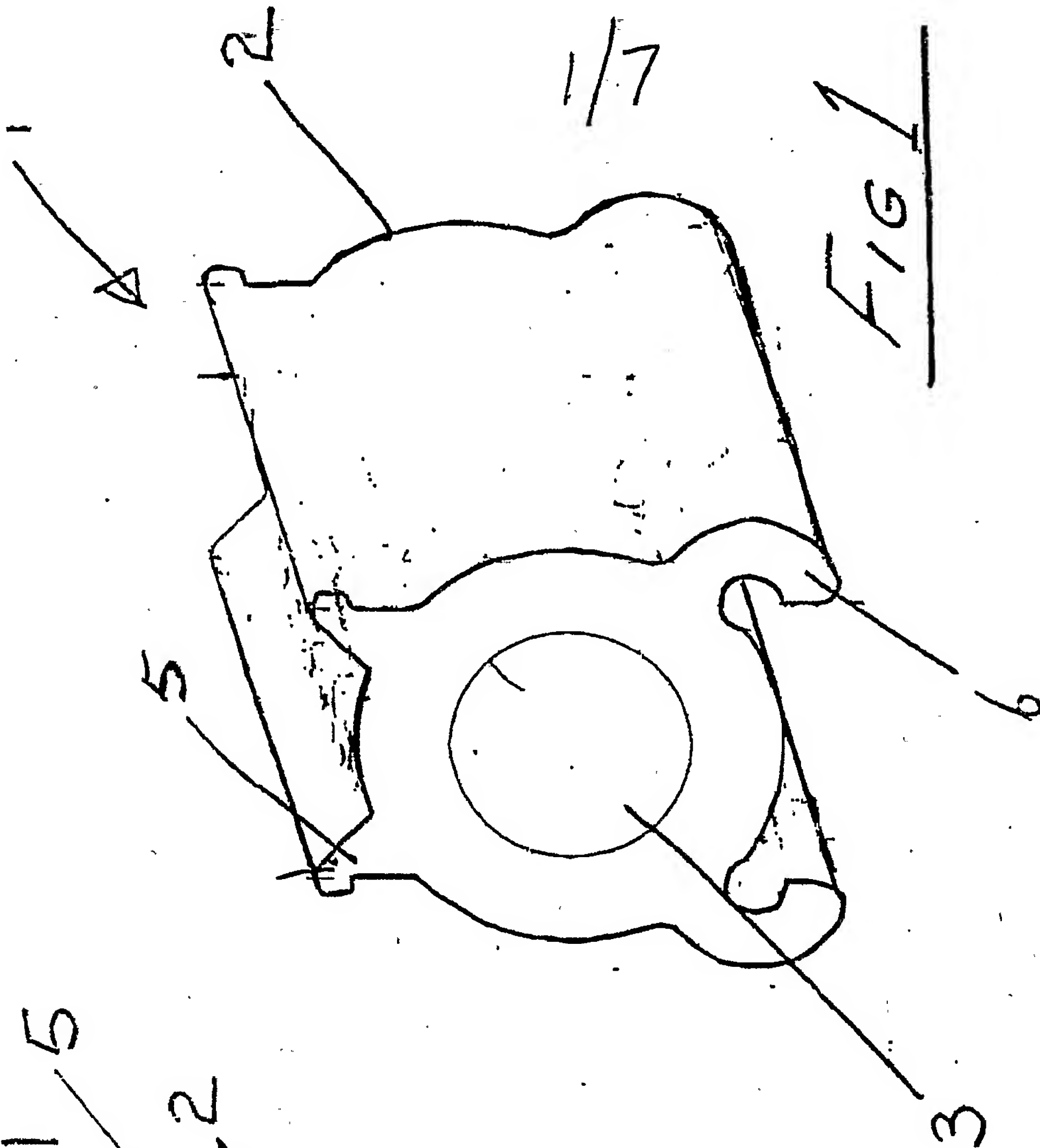
20 Referring to Fig. 15 there is shown an alternative construction of medical packaging device indicated generally by the reference numeral 60 having male members 65 and female members 66 which are rounded. In this construction it can be appreciated that the male members
25 65 and female members 66 can be so dimensioned as to make disassembly difficult during shipping and handling. This rounded construction has the advantage of making manufacture of the medical packaging device 60 easier. It will also facilitate disassembly of the device 60 if
30 enough force is applied.

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Referring to Fig. 16 there is shown an alternative construction of medical packaging device 70 in which the engagement means comprises male and female cooperating members which form a finger lock mechanism. An arcuate male flap 75 defines with the flexible tube 2 a female socket 76 for reception of a bulbous head 77 of the male flap 75.

The invention is not limited to the embodiments hereinbefore described which may be varied in both construction and detail.

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FIG 3

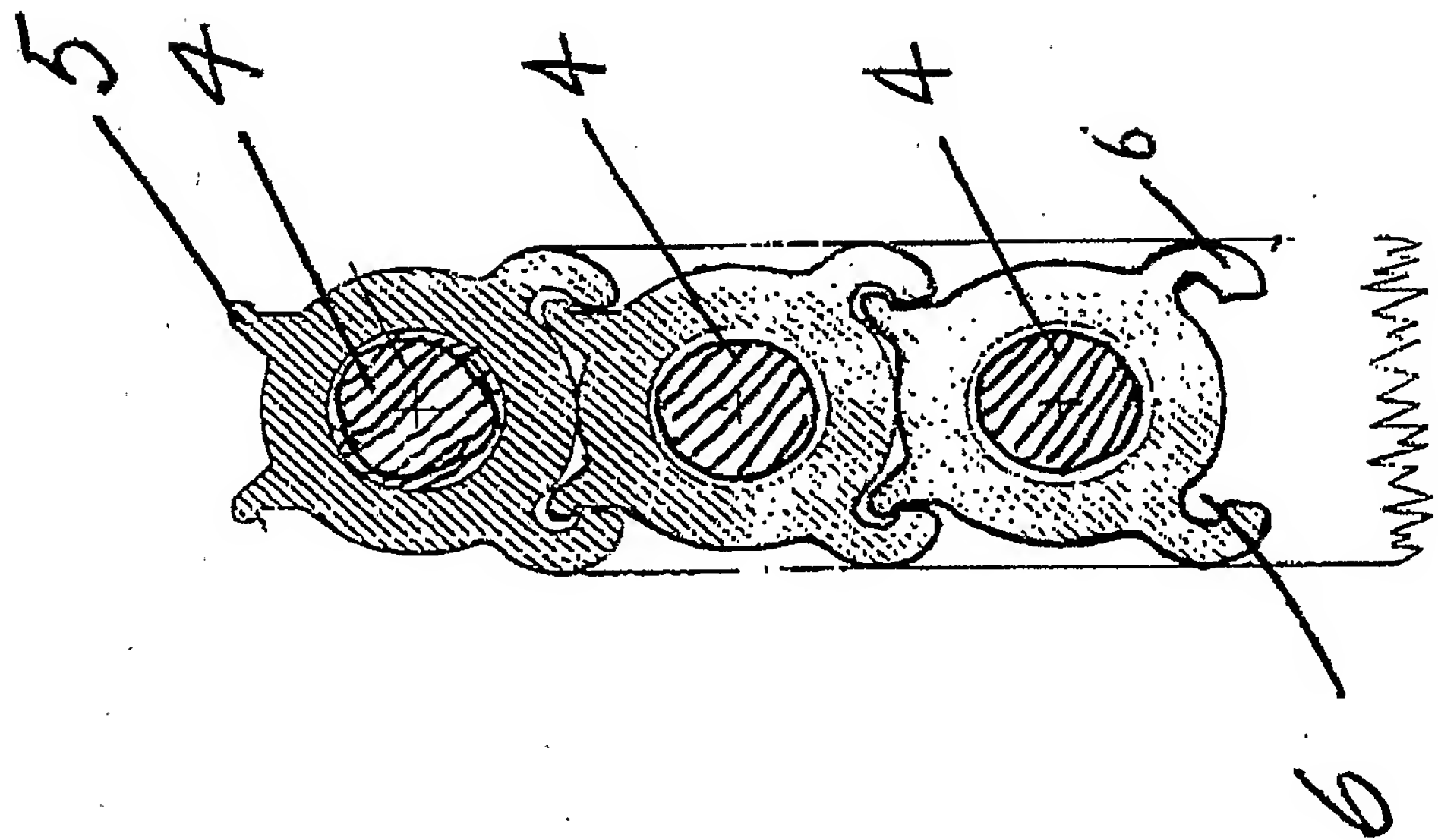
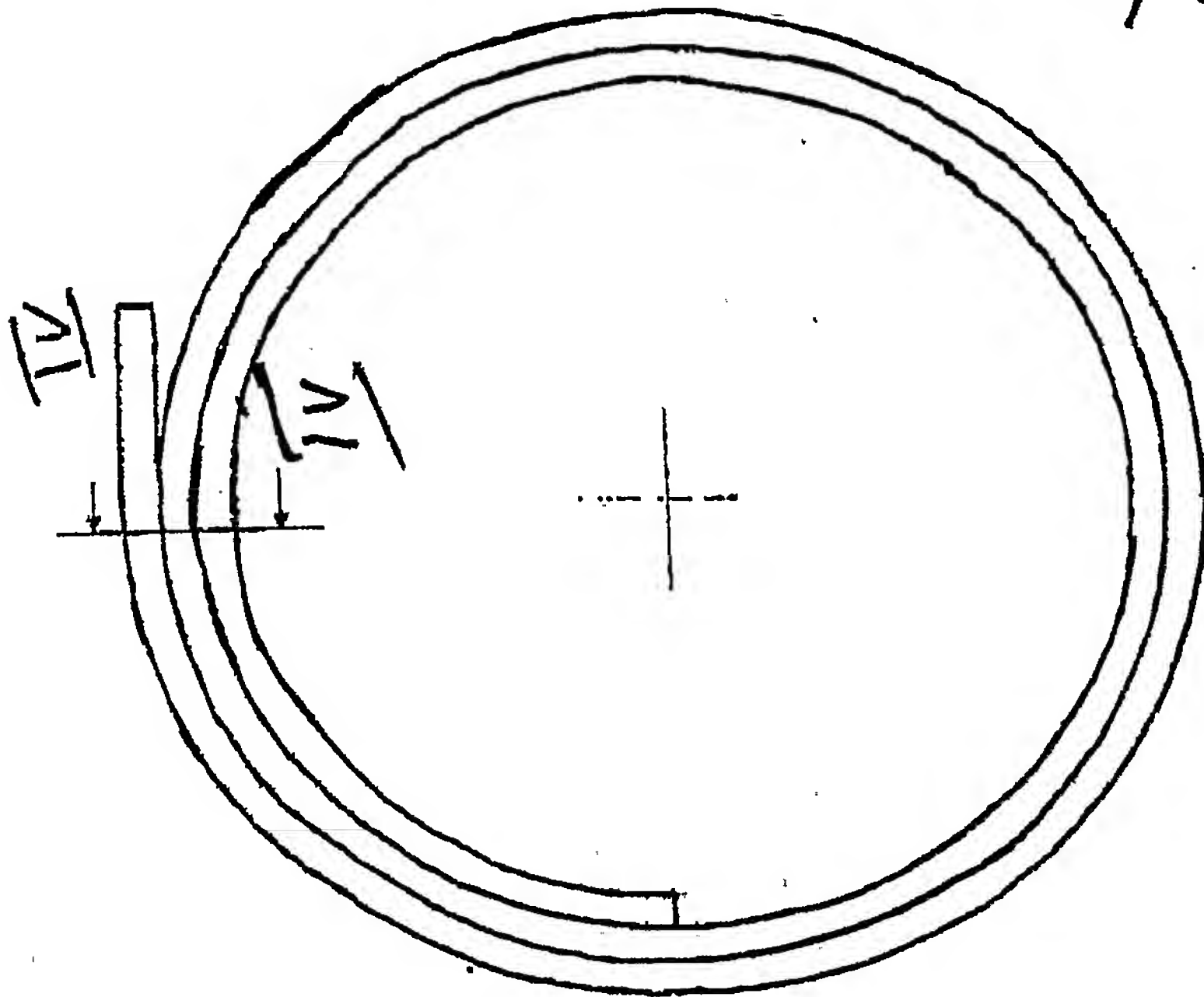


FIG 4

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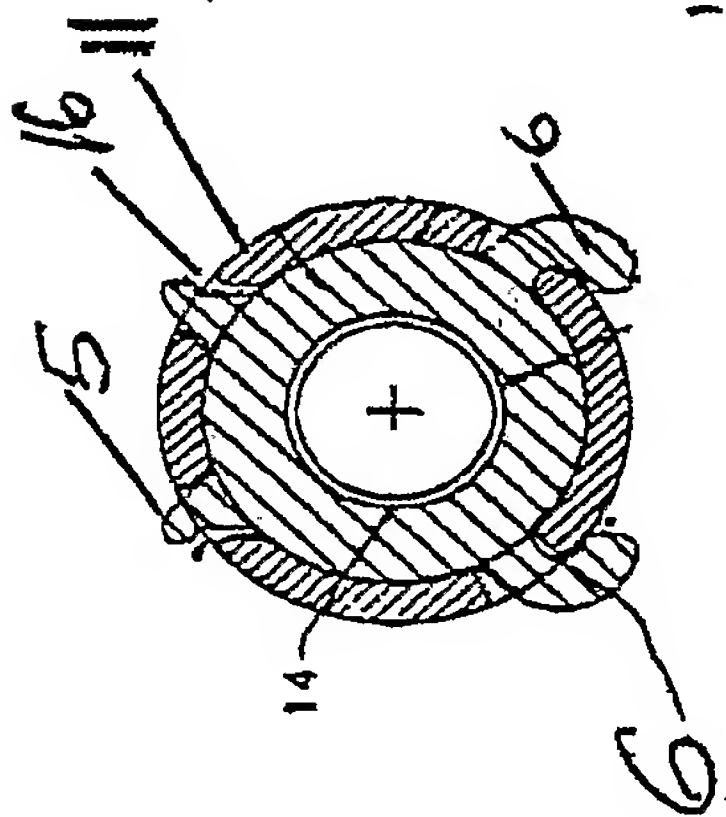
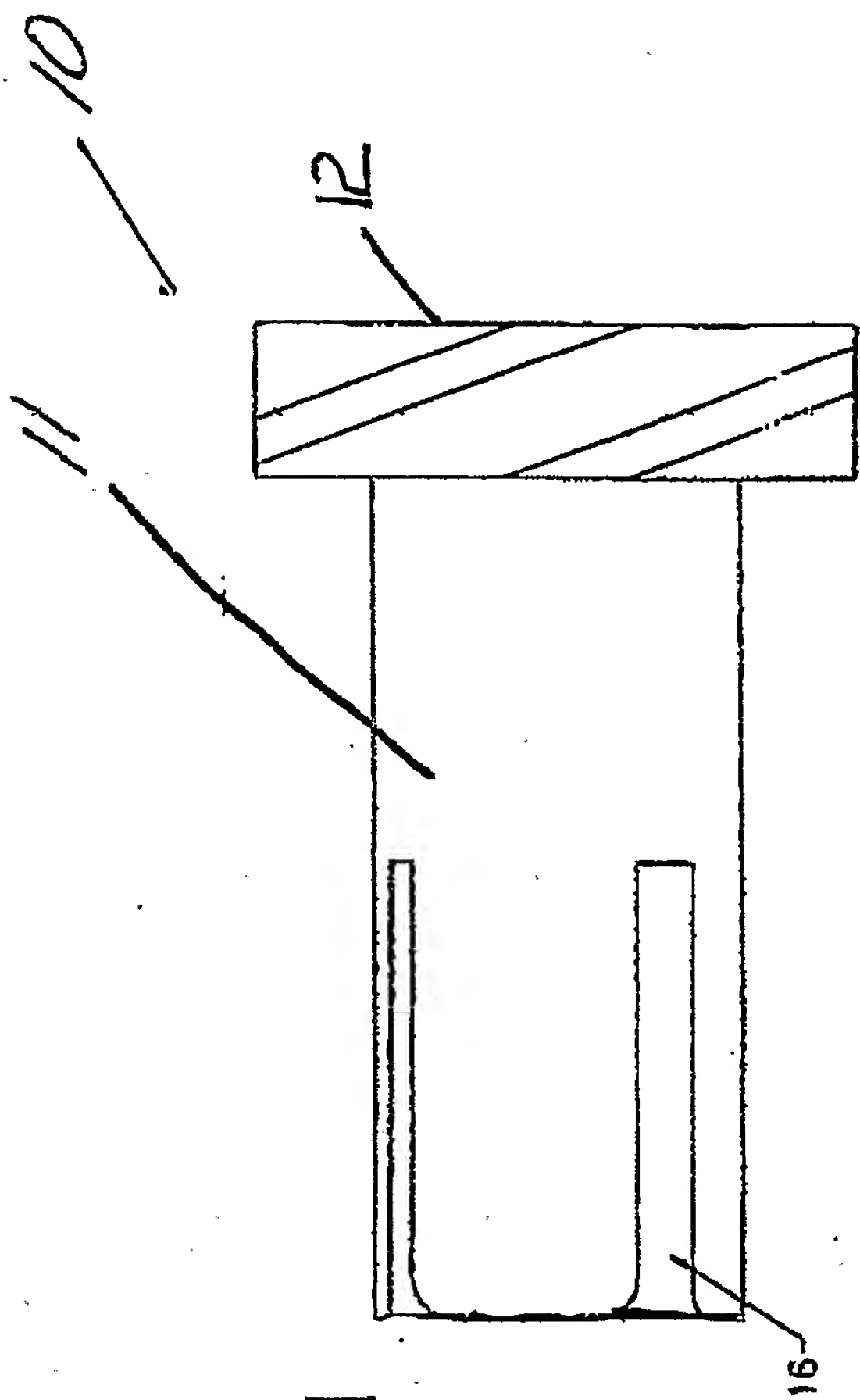


Fig 5

Fig 7

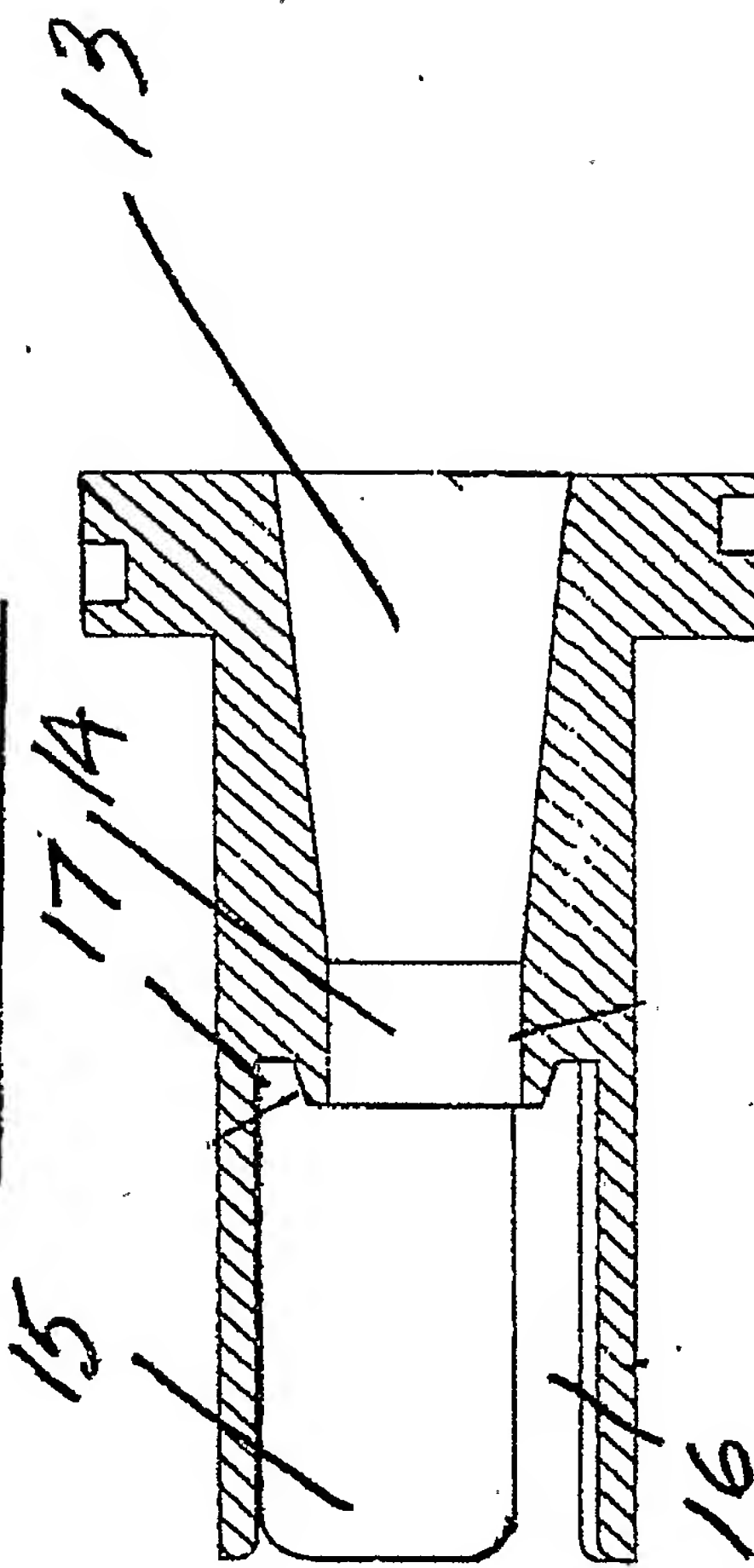


Fig 6

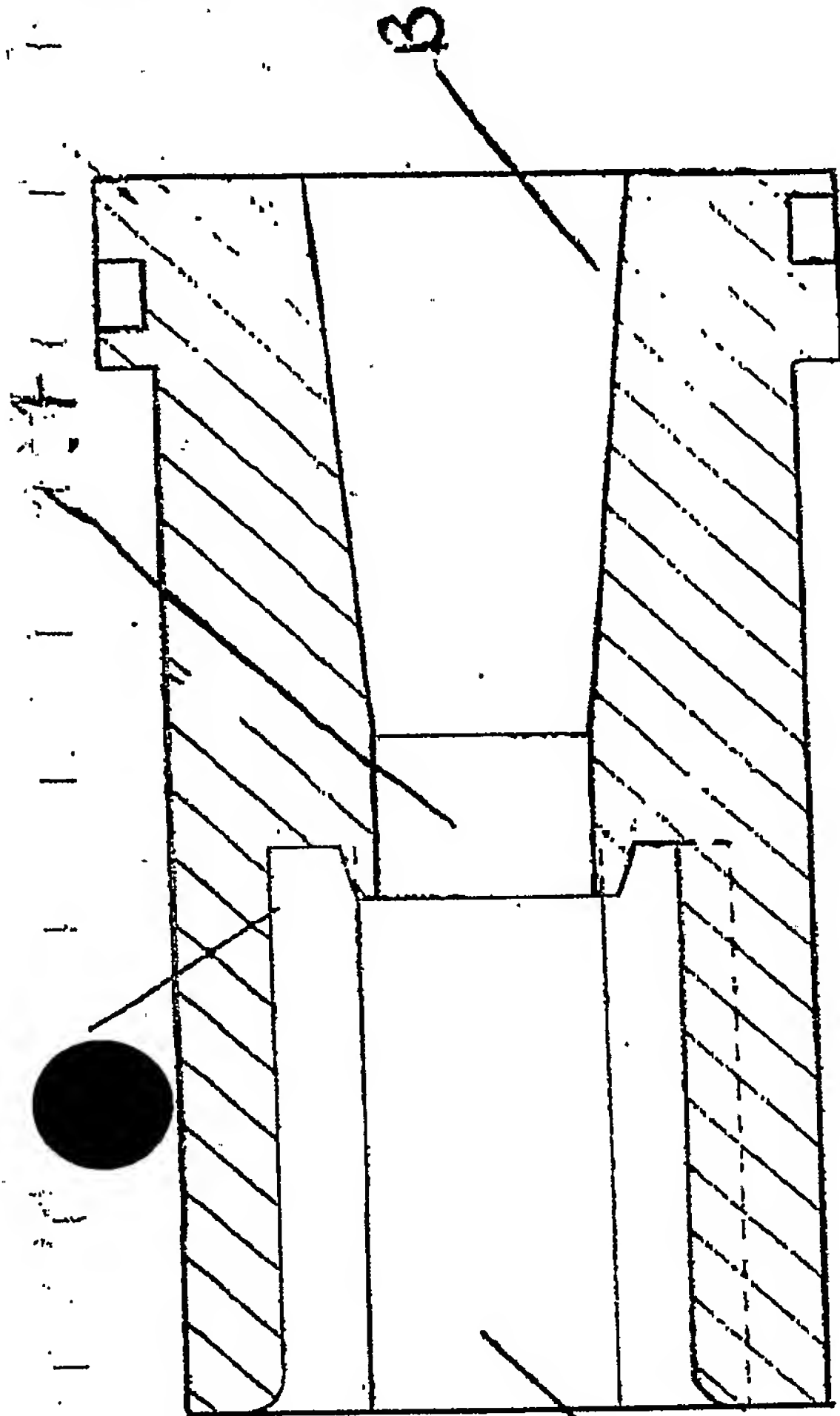


FIG 8

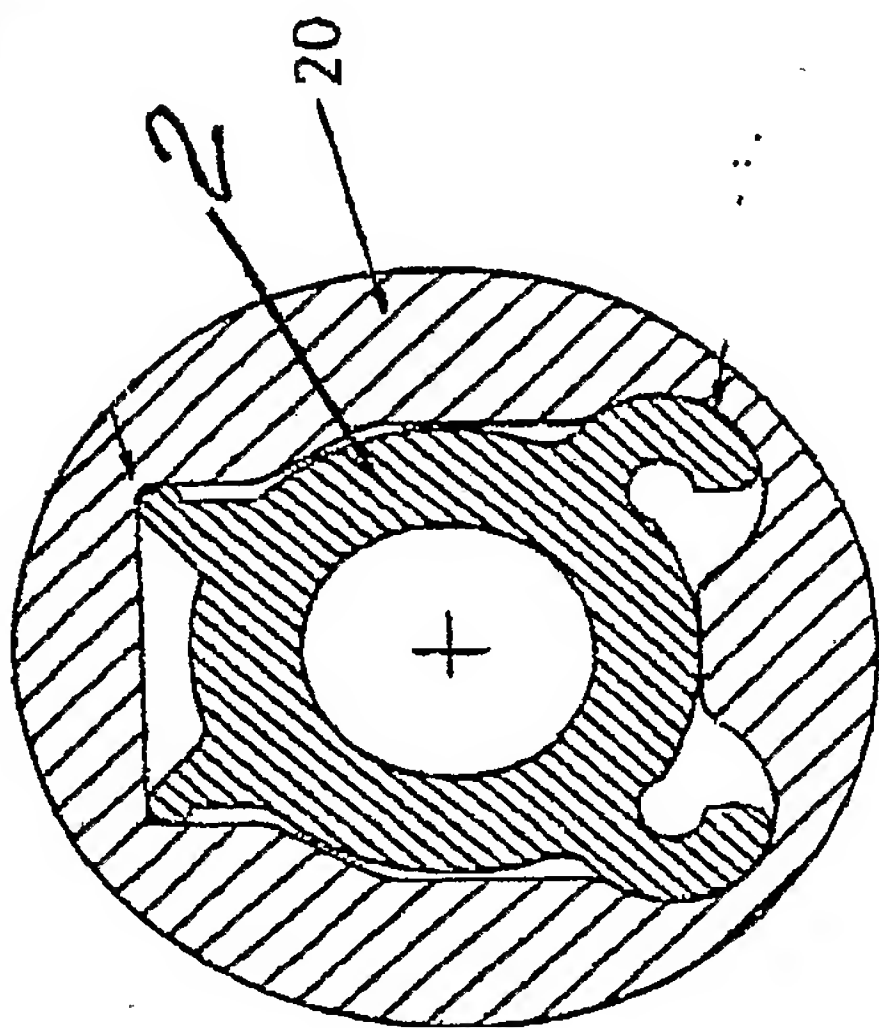


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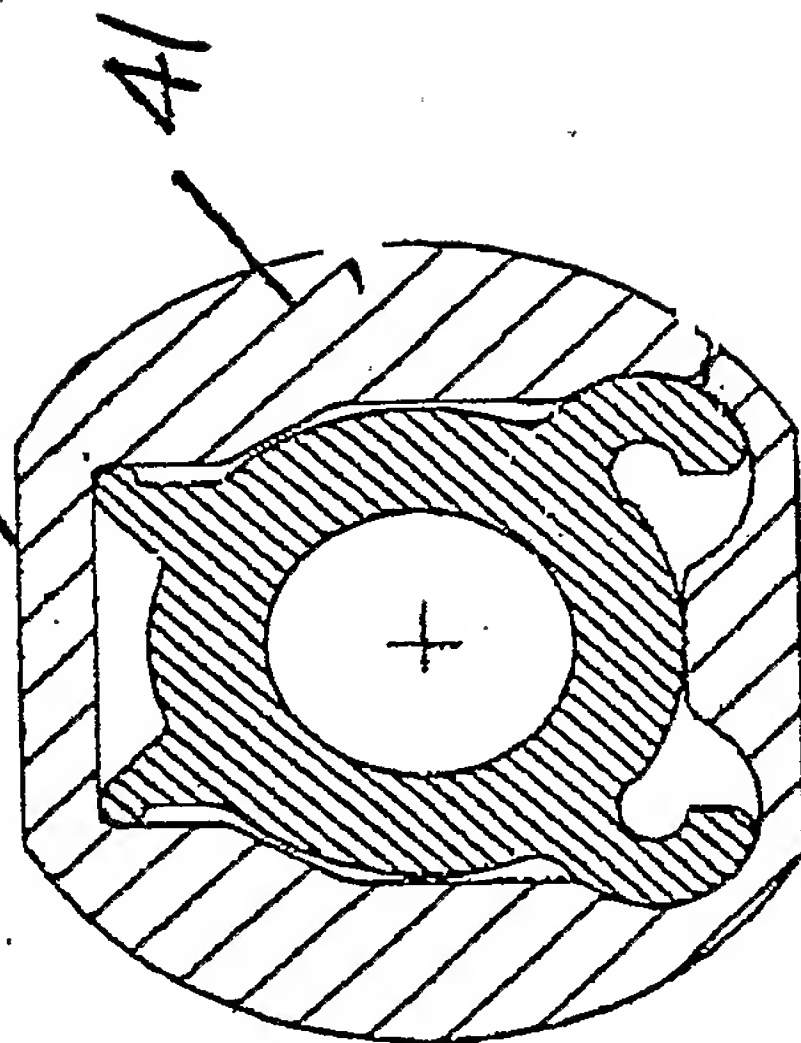


FIG 11

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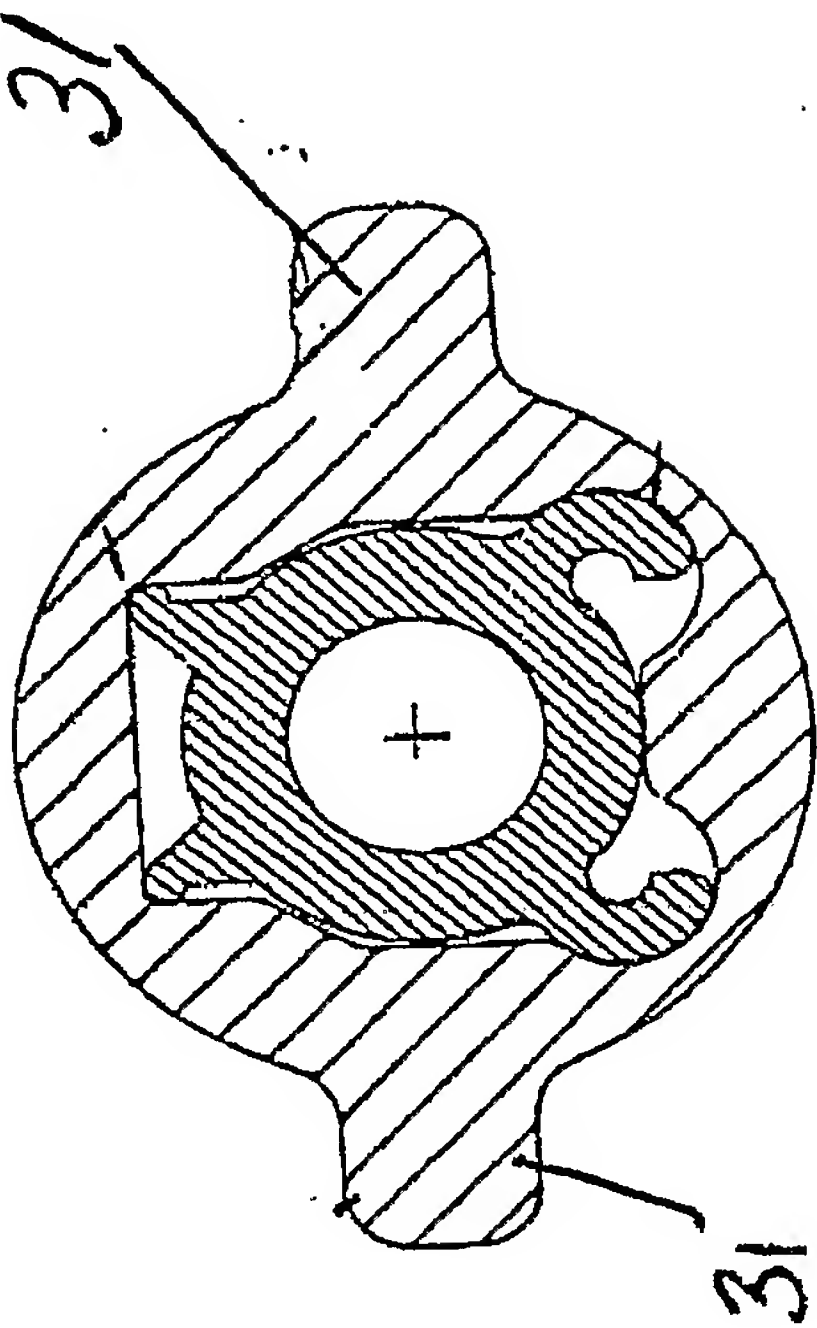
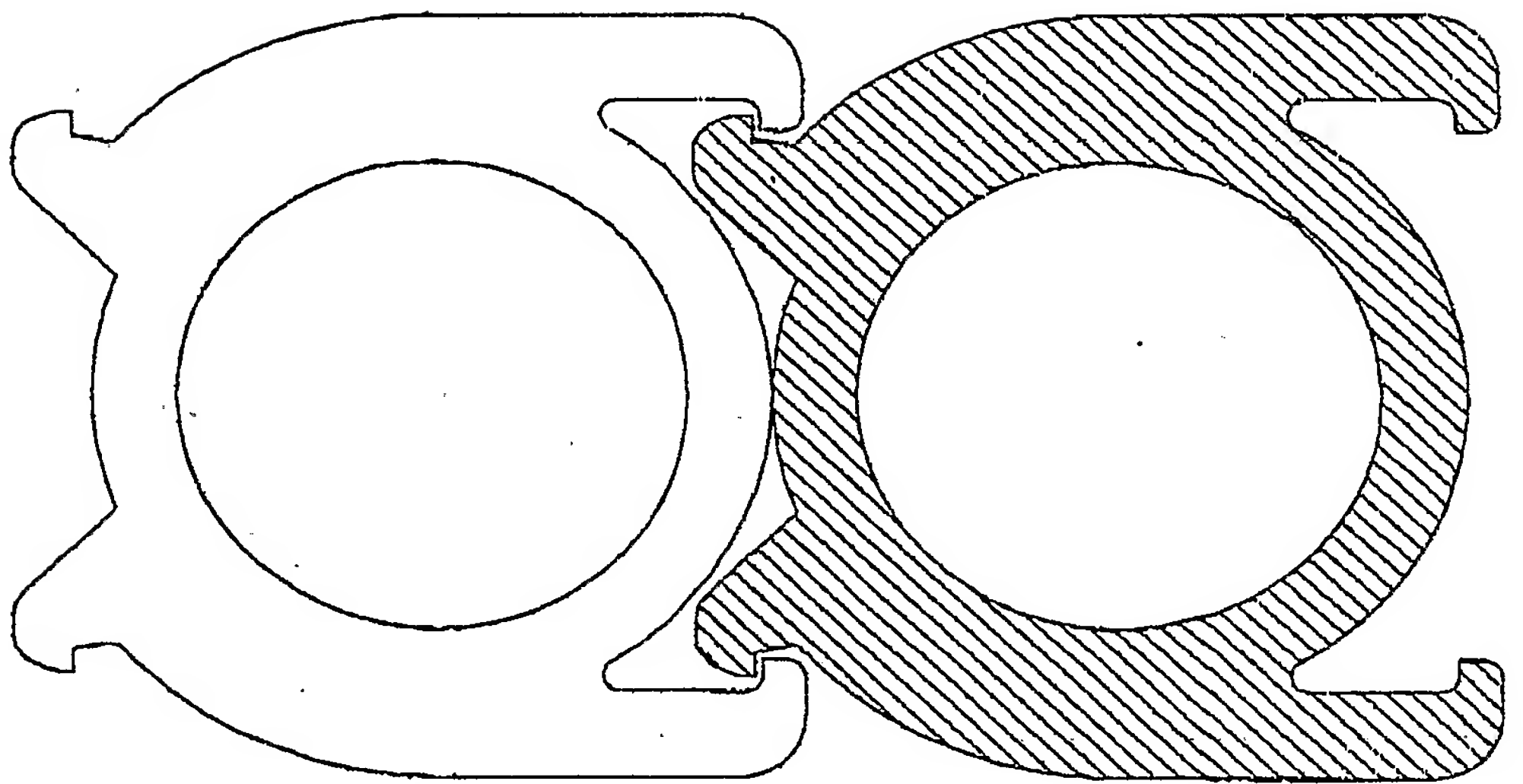
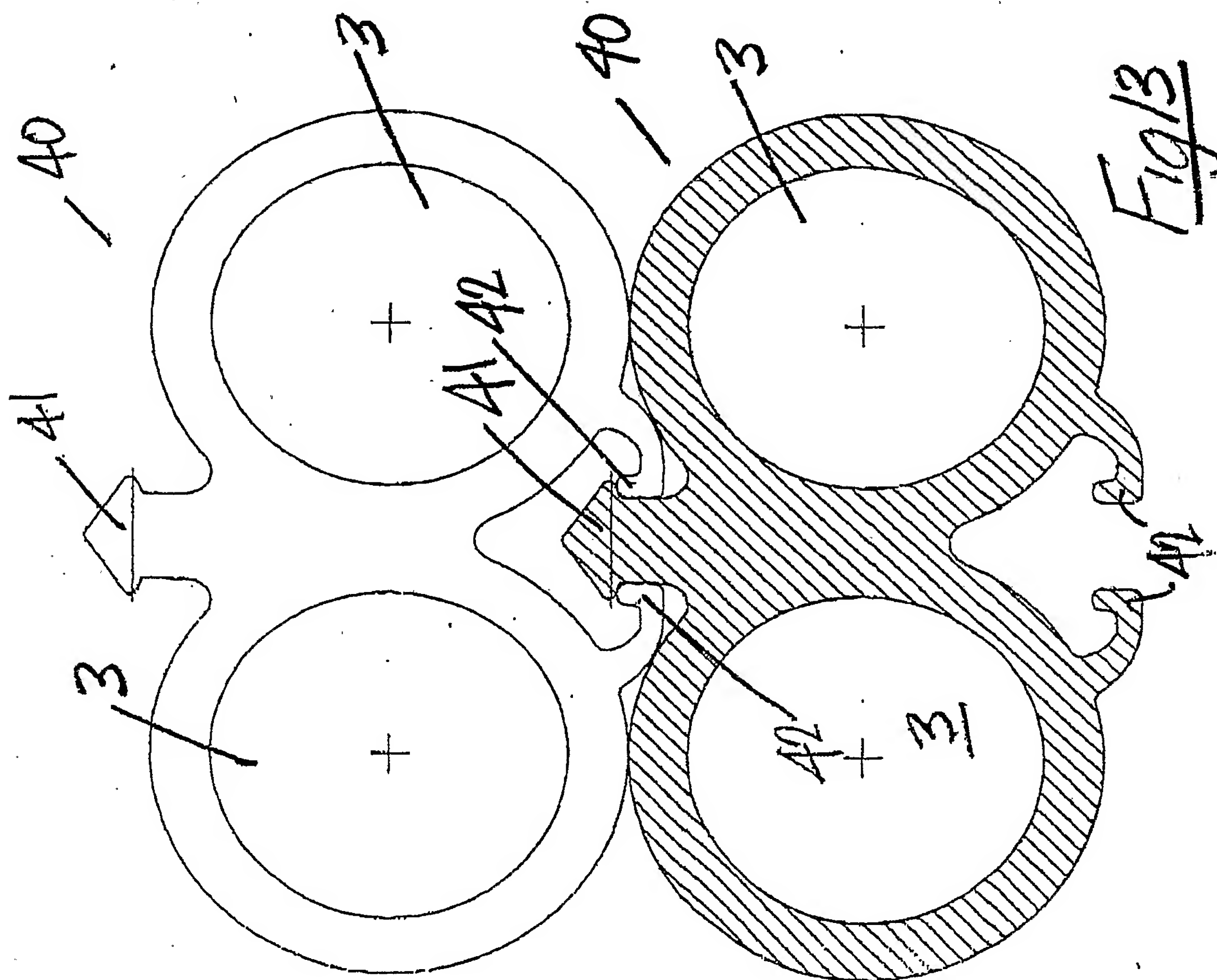
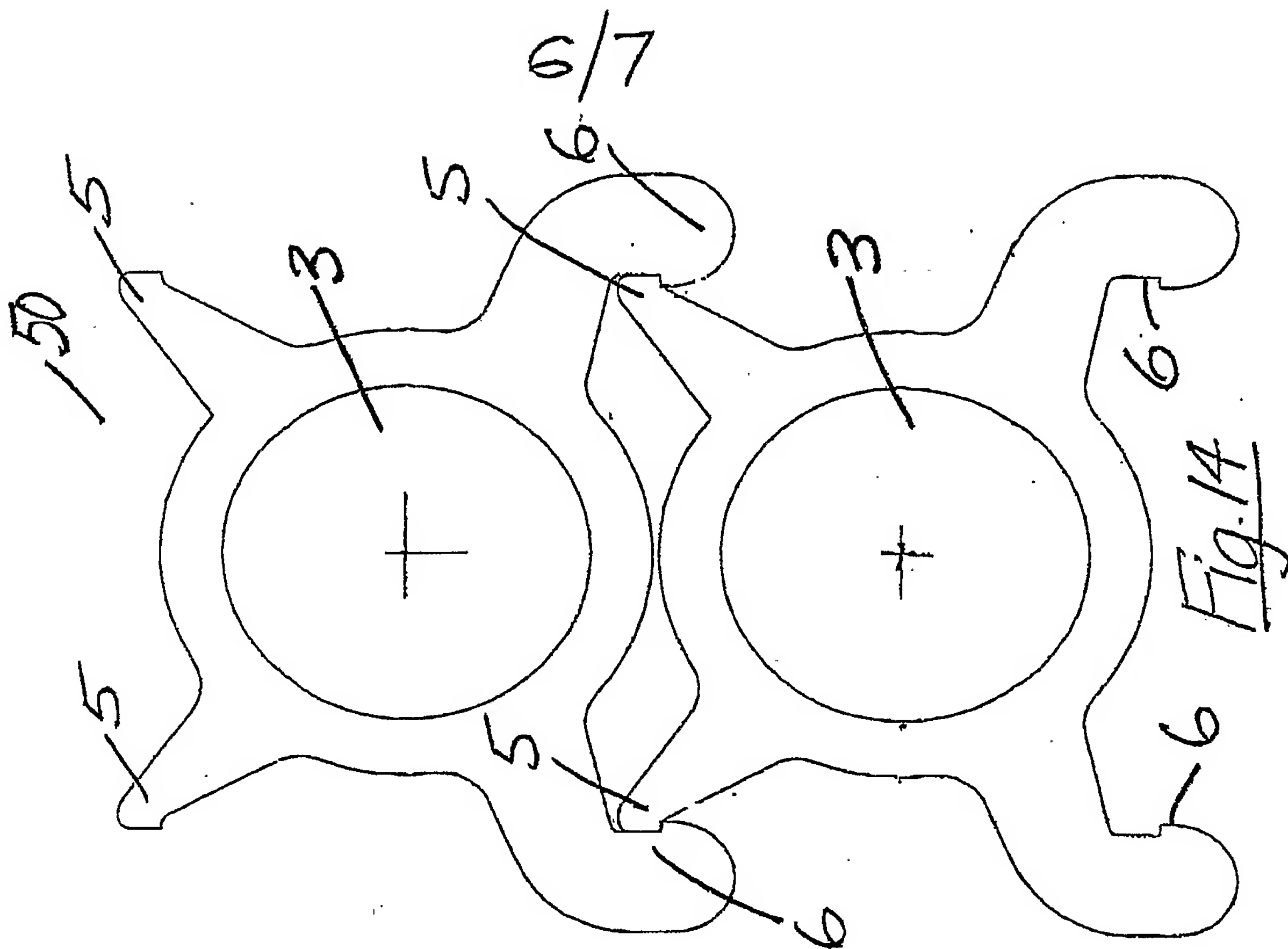


FIG 10

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Fig 12



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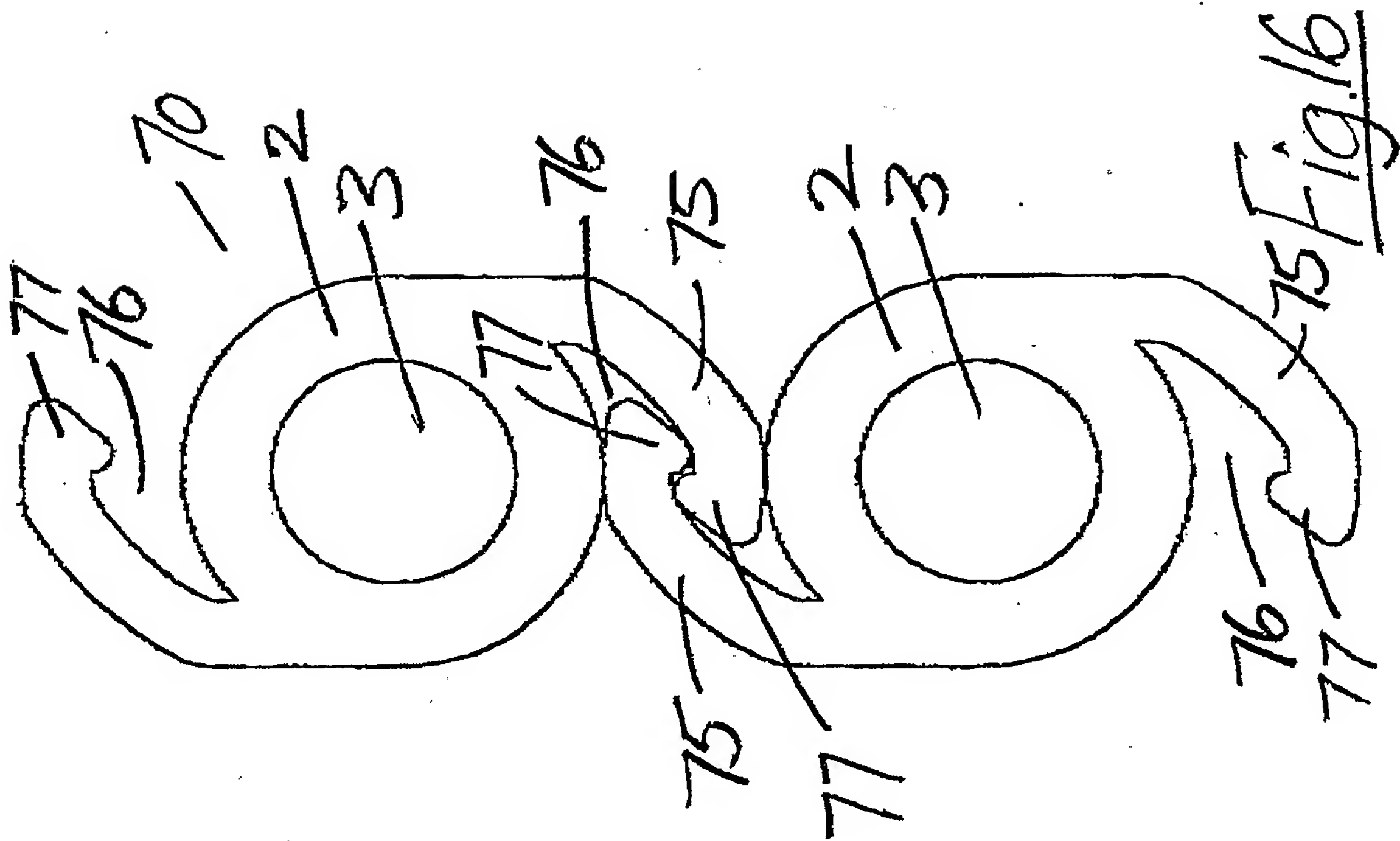


Fig. 16

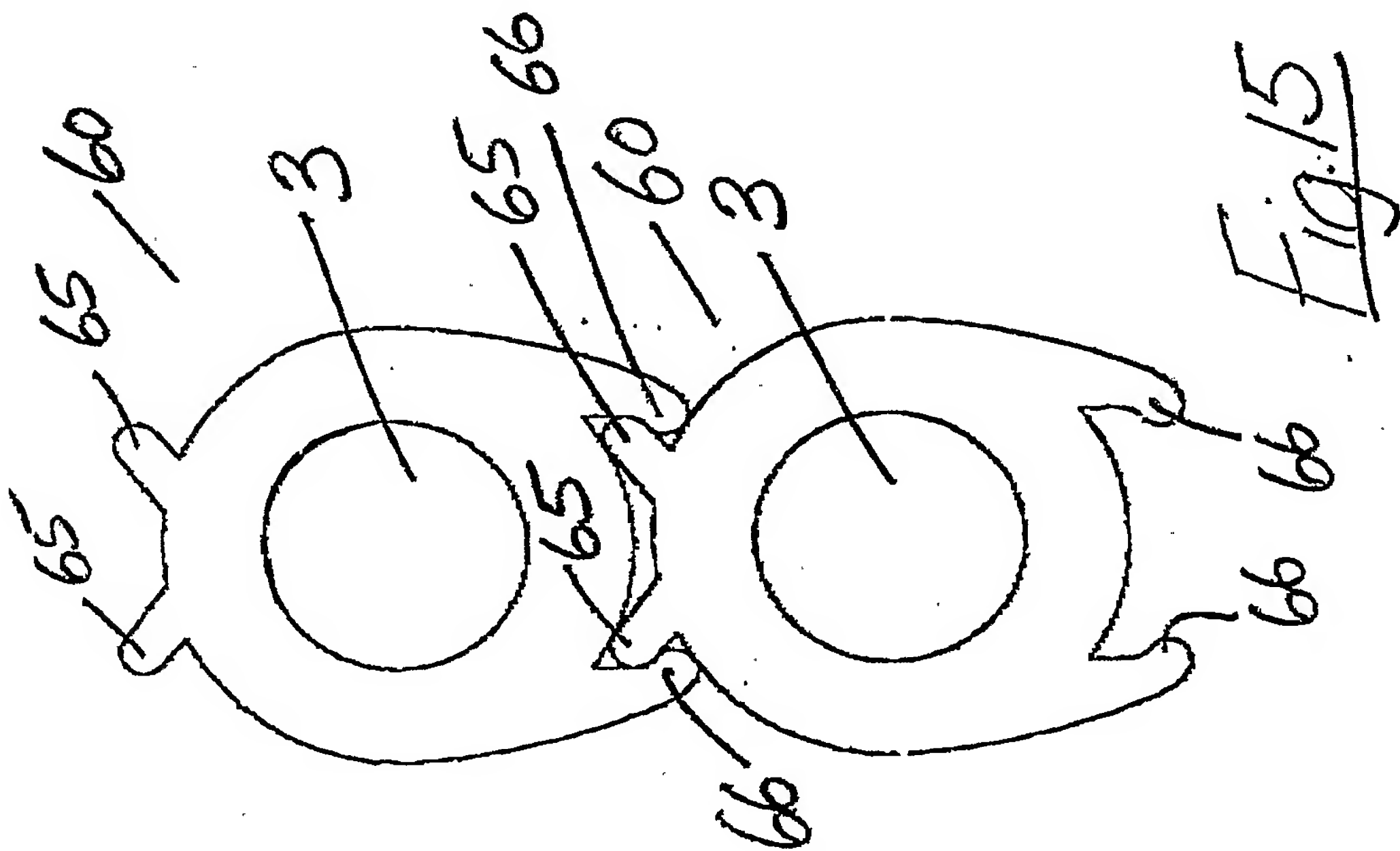


Fig. 15